

REMARKS

Claims 1-2, 5-16, 18-19, 25-33, 35-37 and 41-44 are pending and under examination in the subject application.

Request for Consideration of Reply Filed on December 12, 2006

In the Advisory Action mailed on January 22, 2007, it is indicated both on the cover sheet and on page 2 that applicants' June 27, 2006 reply has been fully considered. Applicants also request full consideration of their reply dated December 12, 2006 if the Examiner has not yet done so.

Rejections under 35 U.S.C. §112, First Paragraph

Claims 1-2, 5-19, 25-33, 35-37 and 41-44 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement for the full breadth of the claims. The Examiner indicated that the specification is enabling for a method of treating and/or imaging melanin containing melanoma in a subject comprising administering an amount of a radiolabeled antimelanin antibody, wherein the antimelanin antibody is 6D2.

Applicants respectfully traverse this rejection.

The application provides examples of the invention using radiolabeled anti-melanin antibody 6D2, as well as using radiolabeled anti-melanin peptide 4B4. In addition to specific examples, the application teaches how to prepare and use radiolabeled antibodies starting at paragraph [0067] on page 16. Furthermore, additional anti-melanin antibodies have been described in the scientific literature. For example, Liu and Jimbow described a monoclonal antibody against phaeomelanin and its major precursor, 5-S-cysteinyldopa (5-S-CD) (Liu and Jimbow, Development and characterization of a murine monoclonal antibody against phaeomelanin and its precursor 5-S-cysteinyldopa, Melanoma Res. 3(6):463-9, 1993; copy of Abstract attached). Rosas et al. described the generation of monoclonal antibodies 6D2 and

11B11 to polymerized fungal melanin (Rosas et al., Synthesis of polymerized melanin by *Cryptococcus neoformans* in infected rodents, *Infection and Immunity* 68(5): 2845-2853, 2000; copy of article attached). In addition, Youngchim et al. described the production of five (5) anti-melanin monoclonal antibodies (Youngchim et al. Production of melanin by *Aspergillus fumigatus*, *J. Medical Microbiology* 53: 175-181, 2004; copy of article attached). These antibodies are reactive with melanin from a variety of sources (Youngchim et al., page 178, left column, Figure 3). Furthermore, Alviano et al. described the isolation of antibodies against melanin from sera of human patients with chromoblastomycosis (Alviano et al., Melanin from *Fonsecaea pedrosoi* induces production of human antifungal antibodies and enhances the antimicrobial efficacy of phagocytes, *Infection and Immunity* 72(1): 229-237, 2004; copy of article attached).

The Examiner cites *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) in rejecting the claims. Applicants respectfully point out in regard to *In re Wands*, as set forth in MPEP §2164.01(a), “[a]fter considering all the factors related to the enablement issue, the court concluded that “it would not require undue experimentation to obtain antibodies needed to practice the claimed invention.” *Id.*, 8 USPQ2d at 1407.”

Finally, applicants note that even if the invention as claimed did read on an inoperative embodiment, “[t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984)” (MPEP §2164.08(b)).

Applicants respectfully maintain that the specification is enabling for the skilled artisan to practice the claimed invention without undue experimentation. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

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Appl. No.: 10/775,869
Filed: February 10, 2004
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CONCLUSIONS

In view of the remarks made hereinabove, reconsideration and withdrawal of the rejections in the September 14, 2006 Final Office Action and passage of the pending claims to allowance are respectfully requested. If there are any minor matters preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

A check in the amount of \$905.00 is enclosed to cover the fees for a small entity for filing a Request for Continued Examination (\$395.00) and for a three month extension of time (\$510.00). No other fee is deemed necessary in connection with the filing of this reply. However, if any other fee is required with this submission or to preserve the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785. Please credit any overpayments to Deposit Account No. 01-1785.

Respectfully submitted,

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By


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